

# Comparison of two analgesic combinations for reno-ureteral colic treatment

<b>Submission date</b> 04/03/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 04/04/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 30/08/2022	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Reno-ureteral colic happens when a stone gets lodged in your urinary tract, often in a ureter. The stone stretches and widens the area, causing intense pain.

The standard treatment consists of a painkiller (diclofenac) given directly via a vein, which is commonly combined with butylhyoscine. Such a combination lacks clinical evaluation in the literature, and a clinical practice guidelines suggest ketorolac and metamizole as second-line treatments. Given the complex behavior of reno-ureteral colic, the ketorolac and metamizole combination may represent a better clinical practice to benefit patients. The present study is aimed to evaluate the efficacy of ketorolac/metamizole versus diclofenac/butylhyoscine for reno-ureteral colic management.

### Who can participate?

Patients with reno-ureteral colic and aged at least 18 years

### What does the study involve?

Patients will be randomly allocated to a single dose of either ketorolac/metamizole or diclofenac/butylhyoscine, and will be monitored from baseline to 45 min.

### What are the possible benefits and risks of participating?

The benefits include evidence-based management for reno-ureteral colic treatment, and the risks for such safe drugs might involve hypersensitivity to formulations.

### Where is the study run from?

Instituto Mexicano del Seguro Social (Mexico)

### When is the study starting and how long is it expected to run for?

September 2021 to September 2022

### Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr Julieta Godoy-Caballero, godoyjulieta957@gmail.com

## Contact information

### Type(s)

Principal Investigator

### Contact name

Dr Julieta Godoy-Caballero

### ORCID ID

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### Contact details

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

R-2021-3201-168

## Study information

### Scientific Title

Analgesic efficacy of ketorolac/metamizole versus diclofenac/butylhyoscine for reno- ureteral colic management in a primary-care hospital emergency service

### Acronym

KMDB

### Study objectives

Ketorolac/metamizole analgesic efficacy is similiar to diclofenac/butylhyoscine in reno-ureteral colic management

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 26/11/2021, IMSS Local Health Research Committee 3201 (Comite Local de investigacion en salud del IMSS 3201, 41 street, Mérida Yucatán, México; no telephone number provided; comite.eticainv@imss.gob.mx), ref: R-2021-3201-168

**Study design**

Single center interventional blinded randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

See additional files (in Spanish)

**Health condition(s) or problem(s) studied**

Reno-ureteral colic management

**Interventions**

Participants will be randomized 1:1 to receive the intervention or the comparison treatment. This process will occur when the patient arrives at the Emergency service from the primary-care hospital and will be performed with sealed envelopes containing the written informed consent, the pain-scale questionnaires, and a colored mark indicating the treatment that should be given.

Patients in the intervention group will receive a single intramuscular dose of ketorolac (30mg) /metamizole (1g).

Patients in the comparison group will receive diclofenac (75mg)/ butylhyoscina (20mg).

Patients are then monitored for 45 minutes.

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Ketorolac, metamizole, diclofenac, butylhyoscine

**Primary outcome measure**

Pain is measured using a visual analogue scale (VAS) at baseline, 10, 20, and 45 min

### **Secondary outcome measures**

The brief pain inventory (short form in Spanish) will be applied to assess the severity of pain and its impact on functioning at baseline

### **Overall study start date**

01/09/2021

### **Completion date**

20/09/2022

## **Eligibility**

### **Key inclusion criteria**

1. Aged 20 to 60 years
2. Clinical signs and symptoms of reno-ureteral colic

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

68

### **Key exclusion criteria**

1. Hypersensitivity to any of the tested drug formulations
2. Patients with severe reno- ureteral colic (with fever and chronic pain)
3. Grade III and IV renal insufficiency
4. Patients will be excluded if they have any pre-existing treatment that might interact with the tested drug
5. Patients will be excluded if they possess pre-existing digestive tube bleeding

### **Date of first enrolment**

01/01/2022

### **Date of final enrolment**

30/04/2022

## **Locations**

### **Countries of recruitment**

Mexico

**Study participating centre**  
**Instituto Mexicano del Seguro Social**  
42 street, Serapio rendon  
Mérida  
Mexico  
97285

## **Sponsor information**

**Organisation**  
Mexican Social Security Institute

**Sponsor details**  
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**Sponsor type**  
Government

**Website**  
<http://www.imss.gob.mx/>

**ROR**  
<https://ror.org/03xddgg98>

## **Funder(s)**

**Funder type**  
Other

**Funder Name**  
Investigator initiated and funded

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal.

### Intention to publish date

01/12/2022

### Individual participant data (IPD) sharing plan

The database will be available upon reasonable request.

godoyjulietta957@gmail.com

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>			10/03/2022	No	Yes
<a href="#">Protocol file</a>		01/11/2021	10/03/2022	No	No